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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,534	09/26/2001	Stefan Bracht	F-7125	9613

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1615	14

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/937,534	BRACHT, STEFAN	
	Examin r	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,8 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,8 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) ✓
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment of Papers Received: Extension of Time and Request for Continued Examination dated 5/6/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (USPN 5,362,496) in view of Yamaguchi et al (USPN 5,820,877) and Majeti (USPN 5,599,554). The claims are drawn to a TTS comprising a backing layer and an adhesive patch, where the patch comprises nicotine as a drug and a monoterpene ketone or essential oil containing the ketone. The claims also recite specific concentrations of the monoterpene ketones present in the invention.

Baker teaches a transdermal or transmucosal formulation comprising a backing layer and an adhesive matrix layer. The transdermal formulation includes nicotine as a drug and essential oils. The essential oils suggested are spearmint and peppermint oil, along with monoterpene ketones and alcohols such as 1-menthol and carvone (col. 6, lin. 6 – 59; col. 20, lin. 26 – 36). The reference states the formulation can be made into both transmucosal and transdermal formulations.

Yamaguchi et al teaches a percutaneous or permucosal patch comprising a backing layer, release liner, an adhesive layer and nicotine as a drug. The patch further comprises a monoterpene alcohol as an absorption enhancers, specifically menthol and mentha oil (col. 4, lin. 18 – 57). The patch is however silent to the inclusion of monoterpene ketones.

Majeti et al teaches transdermal or transmucosal delivery system where the formulation comprises nicotine, and menthol as an additive. The reference also teaches that the delivery system further comprises a backing layer (Abstract; col. 6, lin. 6 – 21).

With regard to the concentration limitations of claims 1 and 15, it is the position of the examiner that these concentrations do not impart patentability on the formulation of applicant. The prior art presents a general combination of components, where applicant merely presents the best mode of their combination, found through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind a skilled artisan would have been motivated to combine the teachings of the art and modify them to provide an optimal presentation. A skilled artisan would have

followed the suggestion of Yamaguchi to include menthol and other monoterpene alcohols into transdermal formulations. This suggestion would have carried over to Baker where both monoterpene alcohols and ketones were suggested (menthol, and carvone), and could be used interchangeably. Though known in the art, Majeti, would have provided the teaching that, formulations for both transdermal and transmucosal delivery are interchangeable and can be prepared similarly. With these suggestions a skilled artisan could have used the structure and support of the backing layer, of either Baker or Yamaguchi, in order to impart support onto the preparation. The artisan would have used the release liner of either Baker or Yamaguchi as well. This would have been motivation enough fro a skilled artisan to include either carvone or menthol into a transdermal preparation comprising nicotine in order to provide better absorption. It would have been obvious to one of ordinary skill in the art to do this with an expected result of a TTS with a supporting backing layer, a release liner, along with an adhesive matrix comprising nicotine and carvone.

4. Claims 6, 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (USPN 5,362,496) in view of Yamaguchi et al (USPN 5,820,877) and Majeti (USPN 5,599,554) all in view Brisken et al (USPN 3559655) and DeFoney et al (USPN 4039653). The claims are drawn to a process for masking the smell of a nicotine containing transdermal patch. The claims recite a specific concentration for a monoterpene ketone used to mask the smell of the nicotine.

As previously discussed above the combination of the teachings of Baker, Yamaguchi, and Majeti render the claimed invention obvious. It is the position of the examiner that this combination also renders the claimed process obvious, by the inherent properties of the

constituents. It is known in the art that mint oil and extracts (monoterpene ketone included) have odor and taste masking properties. As seen in DeFoney et al (col. 9, lin. 15 – 20) and Brisken (col. 7, lin. 1 – 5) it is recognized in the art that these substances mask odors when introduced into formulations. Their presence in the combination discussed above, would inherently mask the odor of the surrounding constituents. Though not disclosed by the reference, given the inherent odor-masking properties of mint oils, and extracts, one of ordinary skill in the art would have been motivated to follow the knowledge in the art in order to mask the odor of the constituents of the TTS. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the knowledge in the art with the expected result of a TTS comprising a suitable backing, and protective layer, useful nicotine suppression therapy.

Regarding the claims 6 and 16, which recite specific concentrations of the monoterpene ketone used for the invention, it is the position of the examiner that these concentrations do not impart patentability on the formulation of applicant. The prior art presents a general combination of components, where applicant merely presents the best mode of their combination, found through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

5. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges

is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to one of ordinary skill in the art to follow the teachings and suggestions of the art. A skilled artisan would have been motivated to use the products of the combination of Baker, Yamaguchi, and Majeti to mask the smells of nicotine present in transdermal formulations. DeFoney and Brisken provides support and teachings that mint oils and their extracts provide taste and odor masking properties to the formulations to which they are added. A skilled artisan would have been motivated to combine these references in order to mask the offensive odor of nicotine. It would have been obvious to one of ordinary skill in the art to combine these references with an expected result of transdermal formulation comprising nicotine and an amount of mint oil extracts sufficient to mask the odor of the nicotine. This patch would be useful smoking reduction therapy.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
July 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600